



UNITED STATES PATENT AND TRADEMARK OFFICE

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Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached applications for patent term extension of U.S. Patent No. 6,107,458 were filed on May 12, 2005 and May 13, 2005, under 35 U.S.C. § 156. Both applications were filed for the above-identified patent, with one application being based upon NDA 21-506, and the other based upon NDA 21-754.

The assistance of your Office is requested in confirming that the products identified in the applications, Mycamine™ (micafungin sodium)(NDA 21-506 and NDA 21-754), have been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. As stated on page 29 and 30 (for NDA 21-754) and page 30 (for NDA 21-506) of the applications for patent term extension, it is noted that applications for patent term extension were also filed for U.S. Patent No. 5,376,634 and 6,265,536.

For NDA No. 21-506, the application for patent term extension states that the fee is \$1060, Since the fee is currently \$1,120, the fee of \$1,120 has been charged.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7744 (telephone) or (571) 273-7744 (facsimile).

Jenny Dey for
Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Oblon, Spivak, McClelland, Maier & Neustadt
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